Remarks

The Pending Claims:

Prior to entry of the above amendments, Claims 1-8, 12-14 and 17 are pending.

Claims 1-4 are directed to an isolated polynucleotide comprising a nucleotide sequence.

Claim 5 is directed to an expression vector comprising the isolated polynucleotide of claim 1.

Claim 6 is directed to a host cell comprising the expression vector of claim 5.

Claim 7 is directed to a transgenic plant comprising the isolated polynucleotide of claim 1.

Claim 8 is directed to a transgenic plant ectopically expressing the isolated polynucleotide of claim 1.

Claim 12 is directed to a method for producing a transgenic plant comprising an isolated polynucleotide.

Claim 13 is directed a method for identifying a sequence homologous to the polynucleotide of claim 1.

Claim 14 is directed to a polynucleotide sequence identified by the method of claim 13.

Claim 17 is directed to a method for screening for a transcription factor that modifies a plant trait.

The Office Action:

Claims 1-8, 12-14 and 17 stand rejected under **35 U.S.C. § 112, first paragraph** as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1 and 5 stand rejected under **35 U.S.C. § 102(b)**, as allegedly being anticipated by Rounsley, et al., or Newman.

Claims 1, 5 and 13-14 stand rejected under **35 U.S.C. § 103(a)**, as allegedly being unpatentable over Newman (GenBank H76020) in view of Newman et al.

Amendments

The applicants' have amended their claims to more particularly point out and distinctly claim what they regard as their invention. Applicants respectfully request entry of the amendments, reconsideration of the application, and timely notice of allowability. Applicants reserve the right to seek patents for subject matter not currently being examined. Applicants believe that no new matter has been added by any of these amendments and that no new search will be required.

The amended claims find support in the specification as a whole and the claims as filed. Claim 1 as amended finds support in the specification as a whole and in particular at claim 1 (h) as filed and on page 17, lines 26-30 and page 39, lines 16-19, where hybridization under stringent conditions is described.

Response to Rejections

In the response that follows, the Examiner's specific objections and rejections are reiterated in small **bold** indented print, followed by Applicants' response, which is identified by normal print.

Finality of Rejection

> **[T] he nucleotide sequences of Newman meet all the limitations to anticipate claim I (f), since each sequence comprises at least 15 consecutive nucleotides of a polynucleotide sequence encoding a polypeptide according to one of SEQ ID NOs: 44, 106, 124, or 128.**

Applicants point out this Office action is the first instance in which claims were rejected under 35 U.S.C. § 102(b) for the reason that Newman (GenBank Accession No: AI100243) anticipates claims that include SEQ ID NO: 128. This new ground for rejection has required a new search on the part of Applicants. Since this is the first instance in which this ground for rejection has been put forth by the PTO, Applicants ask that the Finality of this Office action be withdrawn.

35 U.S.C. § 112, first paragraph

> **Claims 1-8, 12-14 and 17 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.**

Applicant's arguments filed 12-17-01 and 3-1-02 have been fully considered but they are not persuasive. Applicants traverse the rejection on the grounds that one of skill in the art who would have the full length sequence from the sequence listing, could easily make or produce any of the listed fragments. Furthermore, Applicants argue that the specification clearly sets forth both specific sequences encompassed by the claimed invention beyond the SEQ ID NO sequences themselves, and clearly describes a number of other sequences that one of skill in the art possesses from the use of routine techniques employing the sequence sequences.

Contrary, to Applicant's assertions, Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.) Therefore, although one of skill in the art could, by trial and error experimentation, arrive at other isolated polynucleotides encompassed by the limitations of the instant claims, Applicant's methods of isolation does not support Applicant's assertion that they were in possession of the claimed invention at the time of filing of the instant Application. It remains that the claimed polynucleotides encompass all corresponding sequences from other species, mutated sequences, allelic variants, splice variants, sequences that have an unspecified degree of identity (similarity, homology), and so forth. Additionally, it is noted that, the instant claims do not recite any particular function that may be associated with the claimed genus of polynucleotides encompassed by the claimed invention.

Applicants further state that "[t]he PTO then sites to cases, such as Amgen v. Chugai, where the applicant did not even possess the cDNA of the claimed invention encompassing a protein-encoding sequence." It appears that Applicants have misunderstood the Examiner's position set forth in the prior Office Action. Amgen v. Chugai, and other cases were cited to clearly set forth the what the courts have decided in regards to satisfying the requirements of 35 USC 112, first paragraph, specifically concerning the requirement for a sufficient written description of the invention. In summary, *Vas-Cath Inc. v. Mahurkar,* 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention. Fiers v. Revel,* 25 USPQ2d 1601, 1606 (CAFC 1993) and *Amgen Inc. V Chugai Pharmaceutical Co. Ltd.,* 18 USPQ2d 1016, state that an adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. Finally, *University of California v. Eli Lilly and Co.,* 43 USPQ2d 1398, 1404, 1405, also cites Fiers v. Revel, and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., and further determines that "[w]hile the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics- in other words, it thus does not describe human insulin cDNA." The courts have clearly stated that a method of isolating a claimed invention is not sufficient to provide an adequate written description of the claimed invention- a detailed description of the actual chemical structure of the claimed polynucleotide is required.

Contrary to the Examiner's assertion, applicants' specification does indeed sufficiently describe the claimed invention when the appropriate legal standard is applied to the facts of this case. The legal standard for reviewing the written description requirement does not permit the Patent Office to require a particular type of disclosure, such as only a specific chemical structure, to support claims encompassing a particular subject matter. For example, in Amgen, Inc. v. Chugai Pharmaceuticals Co., 18 U.S.P.Q. 2d 1016, 1021 (Fed. Cir. 1991), which the Examiner cites in support of the written description rejection, the court stated that applicants can

demonstrate adequate description of a claimed or recited structure in a variety of ways, including "... its method or preparation, its physical or chemical properties, or whatever characteristics sufficiently distinguish it." The law does not recognize a single, "required" way to sufficiently describe any subject matter.

Furthermore, Applicants submit that the rejection under 35 U.S.C. § 112, first paragraph has been overcome in part by the amendment of claim 1, which is now directed to:

(a) a nucleotide sequence encoding a polypeptide comprising an amino acid sequence selected from the group consisting of SEQ ID NO: 38, 46, 48, 124, 126, and 158;

(b) a nucleotide sequence comprising a sequence selected from SEQ ID NO: 37, 45, 47, 123, 125, and 157;

(c) a nucleotide sequence that hybridizes to the nucleotide sequences set forth in (a) or (b) under the following conditions: hybridization in 42° C in 50% formamide, 5X SSC, and washing with a step selected from the group consisting of (i) 0.2X SSC, 0.05% sodium sarcosyl and 0.01% sodium pyrophosphate at 55° C; (ii) 0.2x SSC to 2.0 x SSC, 0.1% SDS at 50-65° C, and (iii) 0.2 x SSC, 0.1% SDS at 65° C; and

(d) the complement of (a), (b) or (c).

As to sections (a) and (b) of claim 1, the Examiner has conceded that the isolated polynucleotides of SEQ ID NO: 19, 37, 43, 47, 105, 127 and 157 meet the written description provisions of 35 U.S.C. § 112 (*see* Paper No. 5, page 7, lines 15-17). By inference, SEQ ID NO: 20, 38, 44, 48, 106, 128 and 158 also meet the written description provisions, since the former sequences encode the latter (*see* claim 1 as filed), and are specifically disclosed in the specification (*see, for example*, claim 1, pages 3-4, and Table 1, pages 10-13).

As to section (c) of claim 1, the claim is now directed to a third nucleotide sequence that hybridizes to the nucleotide sequences set forth in (a) or (b) under the conditions defined by the amendment. Applicants note that the USPTO has stated that similar claims meet the written description requirement provisions, in particular with regards to the genus being claimed (*see* "Request for Comments on Interim Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112 para. 1 'Written Description' Requirement," 63 Fed. Reg. 32639 (June 15, 1998) (available online at: http://www.uspto.gov/web/offices/com/sol/notices/fr986-27.html) (hereinafter "Guidelines"). The PTO's Guidelines include the following examples of claims meeting the written description requirement:

> The specification discloses the sequence of the isolated DNA molecule consisting of SEQ ID NO: 1 and discloses several sequences that hybridize to SEQ ID NO: 1. Hybridization under the stringent conditions specified here requires that the claimed nucleic acid probes be structurally similar to the complement of the nucleic acid sequence disclosed as SEQ ID NO: 1. In this case, the description as a whole is sufficient to evidence possession of the claimed genus because the genus is defined by relation to the structure of the sequence provided as SEQ ID NO: 1, and because several species are disclosed that possess the hybridization property which further defines the genus. Thus, this claim to a genus meets the [Patent Office's] criteria.
>
> For each claim to a genus not supported as described [above], [if] a representative number of species have been described by complete structure ... then the applicant has written description support for the claimed genus and a rejection under 112 para. 1 for lack of written description must not be made.

Guidelines at 32642.

As to section (d) of claim 1, the Guidelines point out that claims directed to complementary sequences to those specified meet the written description provisions of 35 U.S.C. § 112 (*see* Guidelines at 32641, in which a claim to "an isolated double-stranded DNA consisting of (1) a single-stranded DNA which has a molecular size of 2.57 Kb and is derived from golden mosaic virus, and (2) a DNA complementary to said single-stranded DNA ..." is held to meet the written description provisions). Furthermore, claim 1 (c) specifies hybridization under stringent conditions, and as those of ordinary skill in the art would recognize, the claimed nucleic acids will be structurally similar to the complement of the disclosed polynucleotides, and as stated above, "in this case, the description as a whole is sufficient to evidence possession of the claimed genus because the genus is defined by relation to the structure of the sequence[s] [disclosed]." Guidelines at 32642.

Thus, claim 1, and subsequent claims that are dependent on claim 1 or incorporate the limitations of claim 1, meet the written description requirement of 35 U.S.C. § 112. Accordingly, the Examiner is respectfully requested to withdraw the rejection under 35 U.S.C. § 112, first paragraph.

35 U.S.C. § 102(b)

Claim 1 and 5 remain rejected under 35 U.S.C. 102(b) as being anticipated by Rounsley et al. (GenBank Accession No. B29089), or Newman. (GenBank Accession No: T43527, H76020, T14116 or A1100243) for the reasons of record set forth in the Official Action mailed 7-16-01.

Applicant's arguments filed 12-17-01 have been fully considered but they are not persuasive. Applicants traverse the instant rejection on the grounds that the prior art sequences do not anticipate applicant's amended claim 1, and the claims dependent thereon, as, *inter alia,* they appear to be merely fragments of a gene that has not been expressed in a plant.

First, contrary to Applicant's assertions, the instant claims are not limited to only those nucleotide sequences of a gene that have been expressed in a plant. Secondly, it remains that the instant claims read on (b) a nucleotide sequence encoding a polypeptide comprising a sequence selected from SEQ ID NOs: 20, 38, 44, 46, 106, 124, 126, 128, and 158, *including substitutions, deletions, or insertions;* (f) a nucleotide sequence comprising at least 15 consecutive nucleotides of a polynucleotides sequence encoding an expressed plant polypeptides of SEQ ID NOs: 20, 38, 44, 46, 106, 124, 126, 128, and 158; and (g) the complement of (b). As stated in the prior Official Action, Rounsley et al. discloses a sequence having at least 250 consecutive nucleotides of SEQ ID NO: 19 of the instant invention, which encodes the polypeptide according to SEQ ID NO: 20. Therefore, Rounsley et al. discloses an isolated polynucleotide according to claim 1 part (f) as described above. Additionally, the nucleotide sequences of Newman meet all the limitations to anticipate claim I (f), since each sequence comprises at least 15 consecutive nucleotides of a polynucleotide sequence encoding a polypeptide according to one of SEQ ID NOs: 44, 106, 124, or 128.

Applicants submit that the rejection under 35 U.S.C. § 102(b) is not applicable to the claims as amended.

Amended claims 5, 7, 8, 12, 13, and 17 are directed to "a polynucleotide selected from the group consisting of the isolated polynucleotide of claim 1, SEQ ID NO: 19, SEQ ID NO: 43, SEQ ID NO: 105, and SEQ ID NO: 127." Since the reference sequences cited by the Examiner do not teach an expression vector (*see* Response to Rejection Under 35 U.S.C. § 103(a), *infra*), a host cell comprising the expression vector, a transgenic plant, a method for producing a transgenic plant, a method for identifying homologous sequences, the sequences identified by this latter method, or a method for screening for a transcription factor that modifies a plant trait, the references cited by the Examiner do not anticipate the present claims.

Applicants believe the Examiner may have erred when she referred to the anticipation of SEQ ID NO: 124 (Paper No. 13, page 5, line 4) by Newman (GenBank Accession No. AI100243). This rejection was initially made in the first Office action (Paper No. 5, page 13, lines 1-4). However, Applicants have not been able to identify sufficient alignment of the reference sequence with respect SEQ ID NO: 124 that would provide a reasonable basis for this rejection. The Examiner may have initially meant to refer to SEQ ID NO: 128, rather than SEQ ID NO: 124, the former being the basis for a new rejection.

Accordingly, in light of the current claims and the arguments above, the Examiner is respectfully requested to withdraw the rejection under 35 U.S.C. § 102.

35 U.S.C. § 103(a)

> **Claims 1, 5 and 13-14 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Newman (GenBank H76020) in view of Newman et al., for the reasons of record set forth in the Official Action mailed 7-16-01.**
>
> **Applicant's arguments filed 12-17-01 have been fully considered but they are not persuasive. Applicant traverse the instant rejection on the grounds that the Newman GenBank sequence H76020 does not teach or suggest applicant's amended claim 1. However, as stated above, the nucleotide sequence of Newman (H76020) meets all the limitations of claim 1 (f), e.g., the H76020 sequence contains at least 15 consecutive nucleotides of a polynucleotide encoding a polypeptide according to SEQ ID NO: 44. Applicants also traverse on the grounds that "Applicants have shown in their specification that the recited SEQ Ids of the claims can be used to alter a plant phenotype or trait." Furthermore, Applicants argue, "[t]he rejection offers no reason for expecting that the partial sequence would alter a plant phenotype." However, it is noted that the features upon which applicant relies are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns,* 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).**

Applicants submit that the rejection under 35 U.S.C. § 103(a) has been overcome by the amendment to claim 1, to which the Examiner's arguments regarding the nucleotide sequence of Newman (H76020) is no longer applicable.

Furthermore, regarding claim 5, the Newman references teach lambda PRL2 sequences. Lambda PRL2 is a cDNA library, and hence neither of the references cited teach expression vectors, as taught in claim 5. Since the reference sequences do not teach an expression vector, without hindsight analysis there can be no suggestion or motivation for incorporating the presently claimed sequences in an expression vector. Thus, claim 5 cannot be made obvious by the reference sequences.

Regarding claims 13-14, these reiterated claims incorporate the limitations of amended claim 1, which does not contain references to SEQ ID NOs: 19, 43, 105 or 127, and thus the rejection is not applicable to these claims.

Therefore, the Applicants' claimed invention would not be obvious to one of ordinary skill in the art in light of the Newman references. Accordingly, the Examiner is respectfully requested to withdraw the rejection under 35 U.S.C. § 103(a).

CONCLUSION

If any request for extension of time, petition or fee is required to enter or consider this paper or keep this application pending, including any additional claim fee, applicants hereby request any additional extension or petition necessary and the undersigned authorizes the Commissioner to take the required fees from Deposit Account No. 50-1129.

In view of the above remarks, it is submitted that this application is now ready for allowance. Early notice to that effect is solicited. If in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned at (202) 719-7313.

Respectfully submitted,

Dated: July 16, 2002

David J. Kulik, Reg. No. 36,576
Michael R. Ward, Reg. No. 38,651
Matthew R. Kaser, Reg. No. 44,817
Jeffrey M. Libby, Reg. No. 48,251
Kristin I. Davis, Prov. Reg. No. P-51,599

WILEY REIN & FIELDING LLP
Attn: Patent Administration
1776 K Street, N.W.
Washington, D.C. 20006
202.719.7000 (Telephone)
202.719.7049 (Facsimile)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

ZHANG, et al.

Appl. No.: 09/394,519

Filed: September 13 , 1999

For: PLANT GENE SEQUENCES I

Art Unit: 1635

Examiner: Janet L. Epps

Box AF
Assistant Commissioner for Patents
Washington DC 20231

VERSION OF CLAIMS WITH MARKING TO SHOW CHANGES MADE

These marked-up versions of the claims accompany the attached Response to Final Rejection for the above-identified patent application. Text to be deleted appears in [brackets], and text to be added is underlined.

IN THE CLAIMS

1. (Amended) An isolated polynucleotide comprising a nucleotide sequence selected from the group consisting of:

(a) a nucleotide sequence encoding a polypeptide comprising an amino acid sequence selected from the group consisting of SEQ ID NO: [20,] 38, [44,] 46, 48, [106,] 124, 126, [128,] and 158;

(b) [a nucleotide sequence encoding a polypeptide comprising a sequence selected from SEQ ID NO: 20, 38, 44, 46, 48, 106, 124, 126, 128, and 158, including substitutions, deletions or insertions;

(c)] a nucleotide sequence comprising a sequence selected from SEQ ID NO: [19,] 37, [43,] 45, 47, [105,] 123, 125, [127,] and 157;

[(d) a nucleotide sequence having at least 40% identity with a nucleotide sequence of (a), (b), or (c);

(e) a nucleotide sequence having at least 60% identity with a nucleotide sequence of (a), (b), or (c);

(f) a nucleotide sequence comprising at least 15 consecutive nucleotides of a polynucleotide sequence encoding an expressed plant polypeptide of SEQ ID NO: 20, 38, 44, 46, 48, 106, 124, 126, 128, and 158;]

(c) a nucleotide sequence that hybridizes to the nucleotide sequences set forth in (a) or (b) under the following conditions: hybridization in 42° C in 50% formamide, 5X SSC, and washing with a step selected from the group consisting of (i) 0.2X SSC, 0.05% sodium sarcosyl and 0.01% sodium pyrophosphate at 55° C; (ii) 0.2x SSC to 2.0 x SSC, 0.1% SDS at 50-65° C, and (iii) 0.2 x SSC, 0.1% SDS at 65° C; and

[(g)] (d) the complement of (a), (b) or (c).

2. (Amended) The isolated polynucleotide of claim 1, further comprising a constitutive promoter operably linked to said nucleotide sequence.

3. (Reiterated) The isolated polynucleotide of claim 1, further comprising an inducible promoter operably linked to said nucleotide sequence.

4. (Reiterated) The isolated polynucleotide of claim 1, further comprising a tissue-active promoter operably linked to said nucleotide sequence.

5. (Amended) An expression vector comprising a polynucleotide selected from the group consisting of the isolated polynucleotide of claim 1, SEQ ID NO: 19, SEQ ID NO: 43, SEQ ID NO: 105, and SEQ ID NO: 127.

6. (Reiterated) A host cell comprising the expression vector of claim 5.

7. (Amended) A transgenic plant comprising a polynucleotide selected from the group consisting of the isolated polynucleotide of claim 1, SEQ ID NO: 19, SEQ ID NO: 43, SEQ ID NO: 105, and SEQ ID NO: 127.

8. (Amended) A transgenic plant ectopically expressing a polynucleotide selected from the group consisting of the isolated polynucleotide of claim 1, SEQ ID NO: 19, SEQ ID NO: 43, SEQ ID NO: 105, and SEQ ID NO: 127.

12. (Amended) A method for producing a transgenic plant comprising an isolated polynucleotide or polypeptide, said method comprising (a) providing a polynucleotide selected from the group consisting of an isolated polynucleotide of claim 1, SEQ ID NO: 19, SEQ ID NO: 43, SEQ ID NO: 105, and SEQ ID NO: 127; (b) introducing said isolated polynucleotide in a plant to generate a transgenic plant; and (c) selecting said transgenic plant comprising the isolated polynucleotide or polypeptide.

13. (Reiterated) A method for identifying a sequence homologous to the polynucleotide of claim 1, said method comprising (a) providing a database sequence; (b) aligning and comparing the sequence of the polynucleotide of claim 1 with the database sequence to determine whether the database sequence meets sequence identity criteria relative to the polynucleotide of claim 1; and (c) selecting a database sequence that meets the sequence identity criteria.

14. (Reiterated) A polynucleotide sequence identified by the method of claim 13.

17. (Amended) A method for screening for a transcription factor that modifies a plant trait, said method comprising (a) generating one or more transgenic plants ectopically expressing a polynucleotide selected from the group consisting of an isolated polynucleotide of claim 1, SEQ ID NO: 19, SEQ ID NO: 43, SEQ ID NO: 105, and SEQ

ID NO: 127; and (b) identifying whether said generated transgenic plant is a plant with a modified trait.